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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/604,114	06/26/2000	David J. Farrar		3775

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EXAMINER

WOO, JULIAN W

ART UNIT PAPER NUMBER

3731

DATE MAILED: 02/04/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/604,114

Applicant(s)

FARRAR, DAVID J.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-12,14,15,17,18,20,21,23,24,26,27 and 29-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41-58 is/are allowed.
- 6) ☒ Claim(s) 1,3-12,14,15,17,18,20,21,23,24,26,27,29-40 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 17 is objected to because of the following informality: Claim 17 depends upon claim 16, which is a cancelled claim. Appropriate correction is required. The Examiner presumed that claim 17 is dependent upon claim 15 for the purpose of examination.

Claim Rejections - 35 USC § 112

2. Claims 1, 3-12, 14, 15, 17, 18, 20, 21, 23, 24, 26, 27, 29-40, and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter entails a bypass graft having, inter alia, a flared portion with an interior surface that "does not generate a dilating force" (claim 1) or an exterior surface that "does not generate a shrinking force" (claim 59).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3-6, 18, 21, 24, and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Lau et al. (6,517,570). With respect to claims 1, 3, 18, 21, and 59, Lau et al. disclose, in figure 6 and in col. 14, lines 1-10, a monolithic, polyurethane graft with a tubular portion (adjacent to element 140) and a flared portion (142) having an adjoining end and a flared end, where the flared portion has an elongated circumferential skirt, and where the flared end has an internal diameter greater than an internal diameter of the tubular portion. With respect to claim 24, element 140 is a reinforcing member.

5. Claims 1, 12, 15, 27, 29-32, and 38-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Yang et al. (5,989,287). Yang discloses, in figures 2A and 2B, a monolithic, polyurethane bypass graft (26) with a tubular portion (at 30) and a flared portion (at 42) having an adjoining end and an oblique, flared end, where the flared portion has a circumferential skirt oriented for attaching at an acute angle to a blood vessel (see, e.g., figure 1B), and where the flared end is asymmetrically flared with respect to the central axis of the tubular portion, such that the skirt has a substantially elliptically-shaped circumference

Response to Amendment

6. Applicant's arguments with respect to claims 1, 3, 4, 12 15, 18, 21, 24, 27 29, 30, and 38-40 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

7. Claims 41-58 are allowed.

8. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a method of manufacturing a bypass graft, where at least one layer of polyurethane is formed over a mandrel having a tubular portion and a flared end bulb with a flared end central axis.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

9. Claims 7-11, 14, 17, 20, 23, 26, and 33-37 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a graft formed with at least a layer of polyether urethane-urea with an additive having, in a weight range of 1% to 5%, a combination of MDI, polydimethylsiloxane, and 1,4-butanediol; and where the polyether urethane-urea is end-capped with dibutylamine.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703)308-0858. The FAX number is (703)872-9306.

A handwritten signature in black ink that reads "Julian W. Woo". The signature is written in a cursive, flowing style.

Julian W. Woo
Primary Examiner

February 2, 2004